

**REMARKS**

Claims 1, 2, 6, 8-12, 50, 51, 53-55, 57, 58, and 61-75, 78-84, 87, 88, and 90-112 were pending in this application. Claims 1, 2, 8, 50, 51, 55, 58, 61, 62, 84, 87, 88, 91, 93, 94, 95, 100, 103, and 104 have been amended and claims 64, 66-75, 78-83, and 106-112 have been canceled. In addition, the Examiner has indicated that claims 87, 88, and 90-112 stand withdrawn from further consideration as being drawn to a non-elected invention. Accordingly, upon entry of this amendment, claims 1, 2, 6, 8-12, 50, 51, 53-55, 57, 58, 61-65, 84, 87, 88, and 90-105 will be pending.

Support for the claim amendments presented herein may be found throughout the specification and claims, as originally filed. Specifically, support for the amendments to claims 55 and 58 to recite “a T-box domain” may be found at, for example, page 13, lines 32-33 of the specification; support for the amendments to claims 93 and 94 to recite “a T-box domain” may be found at, for example, page 13, lines 27-28 of the specification; support for the amendments to claims 93 and 94 to recite “at least 600 contiguous nucleotides of SEQ ID NO:3” may be found at, for example, page 15, lines 16-19 of the specification; support for the amendments to claims 8 and 95 may be found at, for example, page 19, lines 28-31 of the specification and in previously examined claims 66, 67, and 107.

*No new matter has been added.* Any amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner’s rejections and was performed solely in the interest of expediting prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

**Allowed Claims and Request for Rejoinder**

The Examiner has indicated that claims 4, 6, and 53 are free of the art and that claims 1-2, 6, 8-12, 51, 53-54, 57, 61-63 65-66, 68-71, and 78-80 are allowed.

Applicants respectfully submit that since the Restriction Requirement between isolated nucleic acid molecules encoding *human and murine* T-bet proteins, vectors, host cells and, methods of producing the protein issued by the Examiner in the January 24, 2005 Office Action was conditioned on the non-allowance of the linking claim, *i.e.*, claim 51, the indication that claim 51 is allowed entitles Applicants to the examination of claim(s) depending from or

otherwise including all the limitations of the allowable linking claim(s). According to M.P.E.P. § 821.04

[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim.

Accordingly, Applicants respectfully request that the Restriction Requirement be withdrawn and that claims 87, 88, and 90-112 drawn to isolated nucleic acid molecules encoding murine T-bet proteins, vectors, host cells and, methods of producing the protein be examined.

**Withdrawal of Certain Rejections**

Applicants gratefully acknowledge the Examiner's indication that the following rejections have been withdrawn:

the rejection of claims 4, 6, 50-51, 53, 57, 64-75, and 78-84 under 35 U.S.C. §112, second paragraph, as being indefinite for the recitation of the term "modulates";

the rejection of claims 4, 6, 50-51, 53, 57, 64-75, and 78-84 under 35 U.S.C. § 112, first paragraph, as containing new matter;

the rejection of claims 4, 6, 50, 53, 64-75, and 78-84 under 35 U.S.C. § 112, first paragraph, for lack of written description; and

the rejection of claims 4, 6, 50-51, 53, 57, 64-75, 78-84 under 35 U.S.C. § 112, first paragraph, for lack of enablement.

***Rejection of Claims 50, 64, and 84 Under 35 U.S.C. § 112, Second Paragraph***

The Examiner has rejected claims 50, 64, and 84 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular the Examiner is of the opinion that

[c]laims 50 and 84 recite that the nucleic acid molecule encodes a polypeptide with an activity including inducing IFN- $\gamma$  production in CD4+ cells and inducing Th1 associated cytokine production. However, claims 50 and 84 depend from claims 6 and 53, respectively, which are limited to nucleic acid molecules encoding polypeptides which induce IFN- $\gamma$

production (a Th1 associated cytokine) in CD4+ cells. Thus, the limitation of inducing IFN- $\gamma$  production in CD4+ cells in claims 50 and 84 is unclear, since it does not further limit the scope of the independent claims. Likewise, the recitation of inducing a Th1 associated cytokine production in claims 50 and 84 renders the claims indefinite, since it actually broadens the scope of the claim already limited to a particular Th1 associated cytokine (IFN- $\gamma$ ).

With respect to claim 64, cancellation of this claim has rendered the Examiner's rejection moot. With respect to claims 50 and 84, Applicants respectfully submit that, without acquiescing to the validity of the Examiner's rejection and solely in the interest of expediting prosecution, the amendments to these claims also render the Examiner's rejection moot. Accordingly, Applicants respectfully request that the rejection of claims 50, 64, and 84 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

***Rejection of Claim 58 Under 35 U.S.C. § 112, First Paragraph***

The Examiner has rejected claim 58 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement." More specifically, the Examiner is of the opinion that

there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of nucleic acids "comprising at least 700 nucleotides which are complementary to at least 700 nucleotides Of SEQ ID NO: 1".

The instant claim is drawn to a genus of nucleic acid molecules that comprise at least 700 nucleotides complementary to 700 nucleotides of SEQ ID NO: 1. It is noted that there is no requirement that said complementary nucleotides be contiguous. Since SEQ ID NO: 1 is a nucleic acid molecule comprising approximately 1600 nucleotides, the claims encompass nucleic acid molecules that are less than 50% identical over the entire length of SEQ ID NO: 1 (*i.e.* complementary over 700 out of 1600 nucleotides). Thus, the claims encompass a wide range of structurally different nucleic acid molecules. Furthermore, the claims do not recite any functional limitations required of the nucleic acid molecules. Furthermore, other than mouse T-bet (SEQ ID NO: 3), the specification does not disclose a single example of nucleic acid molecules that comprise at least 700 nucleotides complementary to SEQ ID NO: 1. The disclosure of a single species is not sufficiently representative of the

broad range of structurally and functionally different nucleic acids molecules encompassed by the claims.

Applicants respectfully traverse the foregoing rejection for at least the reasons set forth below. Claim 58, as amended, is directed to isolated nucleic acid molecules *comprising at least 700 contiguous nucleotides of SEQ ID NO:1 which sequence comprises a T-box domain*, or a nucleic acid molecule comprising a nucleotide sequence complementary to the at least 700 contiguous nucleotides of SEQ ID NO:1 . Applicants respectfully submit that there is sufficient written description in Applicants' specification regarding the claimed nucleic acid molecules, to inform a skilled artisan that Applicants were in possession of the claimed invention at the time the application was filed, as required by section 112, first paragraph (see M.P.E.P. §2163.02). "Written description may be satisfied through disclosure of relevant identifying characteristics, i.e., structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph Written Description Requirement. Moreover, "[a] specification may, within the meaning of 35 U.S.C., § 112, First Paragraph, contain a written description of a broadly written claimed invention without describing all species that claim encompasses." Utter v. Hiraga, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988). Moreover, the In re Grimme case sets out the following language with respect to the written description requirement, "[i]t may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" In re Grimme, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960).

Applicants respectfully submit that the claimed genus of isolated nucleic acid molecules *comprising at least 700 contiguous nucleotides of SEQ ID NO:1 which sequence comprises a T-box domain*, or a nucleic acid molecule comprising a nucleotide sequence complementary to the at least 700 contiguous nucleotides of SEQ ID NO:1 are *defined by structural and functional features that are described in the specification, recited in the claims, and commonly possessed by its members*.

In particular, *the structure of the claimed genus* is taught in the specification, i.e., the sequence, of the nucleic acid molecules of the invention (SEQ ID NO:1) as well as the structure, i.e., the sequence, of the protein encoded by this nucleic acid molecule (SEQ ID NO:2).

Applicants have also provided *functional features common to the claimed genus* of nucleic acid molecules, *i.e.*, the claimed nucleic acid molecules have a T-box domain.

Furthermore, Applicants specification teaches methods routine to one of skill in the art to identify additional T-bet nucleic acid molecules that are at least 700 contiguous nucleotides of SEQ ID NO:1 and have a T-box domain, or nucleic acid molecules that are complementary to the at least 700 contiguous nucleotides of SEQ ID NO:1 (see, e.g., page 15, line 34, through page 16, lines 1-17), natural allelic variants of T-bet (see, e.g., page 16, lines 27, through page 17, lines 1-5), and T-bet DNA sequence polymorphisms (see, e.g., page 16, lines 18-26 of the specification). Applicants' specification also teaches assays that one of skill in the art may use to identify a T-box domain (see, e.g., Figures 1a and 1b, page 13, lines 5-7, page 63, line 27, through page 64, line 13 of the specification).

In summary, Applicants have described a genus of nucleic acid molecules based on structural features that are common to a substantial portion of the genus and have provided within the instant specification the amino acid and nucleotide sequences of this genus that possess these features. Accordingly, Applicants submit that the present invention satisfies the requirements of 35 U.S.C. §112, first paragraph.

***Rejection of Claims 55, 58, 67, 72-75, and 81-83 Under 35 U.S.C. § 112, First Paragraph***

The Examiner has rejected claims 55, 58, 67, 72-75, and 81-83 under 35 U.S.C. §112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." In particular, the Examiner is of the opinion that

[t]he instant claims encompass a genus of nucleic acid molecule fragments comprising at least 700 nucleotides of SEQ ID NO: 1. The disclosed use for the claimed nucleic acid molecules relates to their ability to encode a DNA binding protein that is capable of activating IFN- $\gamma$  transcription. It is known that the DNA binding domain of T-bet protein is encoded by an approximately 600 nucleotide region of SEQ ID NO: 1 (see Szabo *et al.*, Fig. 1, of record). Since the entire T-bet nucleic acid molecule of SEQ ID NO: 1 comprises more than 1600 nucleotides, the instant claims encompass fragments that do not even comprise a DNA binding domain. While the instant specification might enable one of ordinary skill in the art to use a fragment of a T-bet nucleic acid molecule that comprises the

DNA binding domain, the instant specification does not enable one of skill in the art to use the nucleic acid molecules as broadly claimed.

With respect to claims 67, 72-75, and 81-83 cancellation of these claims has rendered the Examiner's rejection moot. With respect to claims 55 and 58, Applicants respectfully traverse the foregoing rejection and submit that one of ordinary skill in the art would be able to make and use the claimed invention using only routine experimentation. Claim 55, and dependent claim 8, as amended, are directed to *isolated nucleic acid molecules consisting of at least 700 contiguous nucleotides of SEQ ID NO:1 which sequence comprises a T-box domain, or a nucleic acid molecule consisting of a nucleotide sequence complementary to the at least 700 contiguous nucleotides of SEQ ID NO:1*. Similarly, claim 58, and dependent claim 8, as amended, are directed to *isolated nucleic acid molecules comprising at least 700 contiguous nucleotides of SEQ ID NO:1 which sequence comprises a T-box domain, or a nucleic acid molecule comprising a nucleotide sequence complementary to the at least 700 contiguous nucleotides of SEQ ID NO:1*. As discussed above, Applicants' specification teaches how to make and use the claimed nucleic acid molecules. Specifically, Applicants' specification teaches the nucleotide sequence and amino acid sequence of such molecules, as well as art recognized methods of generating such molecules. Applicants' specification further teaches methods to identify T-box domains. Thus, one of skill in the art would be able to make and use the claimed nucleic acid molecules with only routine experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph rejection of claims 55, 58, 67, 72-75, and 81-83.

**SUMMARY**

In view of the above amendment, applicant believes the pending application is in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

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Respectfully submitted,

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